

### REMARKS

The present document is submitted in response to the final Office Action dated August 2, 2007 ("Office Action").

Applicants have cancelled claims 12-15 and added new claims 16-25. Support for the new claims appears at various places in the specification, e.g., pages 21-23, paragraph [0062]. No new matter has been introduced.

Upon entry of the present amendments, claims 1-10 and 16-25 will be pending. Among them, claims 1-10 have been withdrawn from consideration and claims 16-25 will be examined. Applicants respectfully request that the Examiner reconsider this application in view of the following remarks.

#### 35 U.S.C. § 112 Rejection

Claims 13-15 are rejected as indefinite on various grounds. Applicants have cancelled these claims, rendering the rejection moot.

#### 35 U.S.C. § 103 Rejection

Claims 12-15 are rejected as obvious over Guire et al, US Patent No. 4,826,759 ("Guire") in view of Reinke et al. ("Reinke"). Applicants have cancelled these claims.

New claims 16-25, submitted in the present document, will be under examination. Applicants address below the Examiner's ground for rejection as applied to these new claims.

Independent claim 16 will be discussed first. This claim covers an immunoassay kit for detecting an analyte e.g., thromboxane B2, in a test sample. The kit includes two strips: (1) the first strip contains a test patch containing a predetermined amount of an antibody specific to an analyte, the antibody being linked to a reporter molecule capable of releasing a signal; and (2) the second strip, made of an absorbent material, is designed for absorbing a test sample containing the analyte.

Guire discloses an apparatus for chemical analysis of an analyte, having two bibulous elements. The first bibulous element contains a chemical reaction system including a member of a ligand-receptor pair that is not labeled (e.g., an antibody specific

to an analyte), and the other member of the pair (e.g., the analyte) that is linked to a label (e.g., an enzyme). The unlabeled member is immobilized on the first element. The second bibulous element includes a label detection system responsive to the label (e.g., the enzyme) to produce a signal. See claims 1 and 5.<sup>1</sup>

The kit of claim 16 differs from the Guire apparatus in at least two aspects:

First, while the Guire apparatus contains a bibulous element loaded with a label detection system (i.e., the second bibulous element), the kit of claim 16 does not include such an element. As pointed out above, claim 16 covers a kit that includes a first strip containing a labeled antibody specific to an analyte, and a second strip for absorbing a test sample containing the analyte. This claim also requires that the first strip (containing labeled antibody molecules) be designed such that, when contacting it with the second strip absorbed with a test sample (containing the analyte), the labeled antibody molecules bound to the analyte will migrate from the first strip to the second strip, while the labeled antibody molecules not bound to the analyte remain on the first strip. The level of signal released from the remaining labeled antibody molecules thereby indicates the amount of the analyte in the test sample. See the specification, page 23, lines 6-9. Of note, the signal is determined after separating the first and second strips. Thus, if a label detection system is needed for determine the signal, the system should be added to the first strip after its separation from the second strip, not included in either the first or the second strip of the claimed kit. Put it in another way; if a detection system is contained in one of the two strips, it would detect the signal released from all of the labeled antibody molecules on the first strip when it contacts the second strip, not only the signal released from the labeled antibody molecules remaining on the first strip after its separation from the second strip, as required by claim 16. In other words, the kit of claim 16 does not

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<sup>1</sup> the Examiner asserts that Guire, at column 7, line 58 through column 8, line 57, and in claim 5, discloses an apparatus containing two bibulous elements, one containing different, predetermined amounts of enzyme-labeled analytes and the other loaded with an anti-analyte antibody. See the Office Action, page 6, second paragraph. Applicants would like to point out that the Examiner has misinterpreted this reference. Indeed, claim 5 in Guire covers an apparatus having: (a) a first bibulous element that contains both enzyme-labeled analytes and an anti-analyte antibody, and (b) a second bibulous element that contains a label detection system. Clearly, the second bibulous element does not contain the anti-analyte antibody as incorrectly asserted by the Examiner.

include a strip corresponding to the second bibulous element of the Guire apparatus, i.e., an element containing a label detection system.

Second, the kit of claim 16 includes a particular strip for absorbing a test sample while the Guire apparatus does not. As pointed out above, the kit of claim 16 requires two different strips, one for loading an antibody (the first strip) and the other for absorbing a test sample (the second strip). The Guire apparatus, however, requires adding a test sample to the first bibulous element, i.e., the element containing both an anti-analyte antibody and enzyme-labeled analytes. See column 8, lines 33-39. Thus, unlike the kit of claim 16, the Guire apparatus uses the same bibulous element for antibody loading and test sample absorption. This reference does not suggest an element corresponding to the second strip of the claimed kit, i.e., a strip only for absorbing a test sample.

In view of the two differences pointed out above, Guire does not suggest the kit of claim 16. Applicants agree with the Examiner that "Reinke discloses thromboxane B2-BSA conjugates, monoclonal antibodies specific to thromboxane B2 and three different types enzyme detection system." See the Office Action, pages 6-7, bridging paragraph. Since this reference does not suggest the kit of claim 16, it does not cure the deficiency of Guire. Applicants thus submit that Guire and Reinke, either taken alone or in combination, do not render claim 16 obvious. Nor do they render obvious claims 17-25, all of which depend from claim 16, directly or indirectly.

It is respectfully requested that the Examiner withdraw this rejection.

### CONCLUSION

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any

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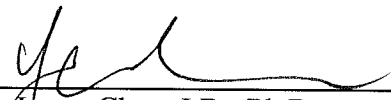
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claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

The Petition for Extension of Time fee in the amount of \$ 230 is being paid concurrently herewith on the Electronic Filing System (EFS) by way of Deposit Account authorization. Please apply any other charges to Deposit Account No. 50-4189, referencing Attorney Docket No. 77101-002002.

Respectfully submitted,

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